What is claimed is:

1. A medical device, comprising:

a substrate that is expandable from a compressed state to an expanded state;

a coating on said substrate, said coating having a drug agent incorporated therein; and

a sheath over said coating, said sheath being expandable from a compressed state to an expanded state and having at least one perforation therein;

wherein when said substrate is in a compressed state, said sheath is in a compressed state and said at least one perforation is substantially closed such that said drug agent does not pass through said at least one perforation; and

wherein when said substrate is in an expanded state, said sheath is in an expanded state and said at least one perforation is substantially open such that said drug agent passes through said at least one perforation.

2. The device of claim 1, wherein said coating comprises a polymer selected from the group consisting of polycarboxylic acids, cellulosic polymers, gelatin, polyvinylpyrrolidone, maleic anhydride polymers, polyamides, polyvinyl alcohols, polyethylene oxides, glycosaminoglycans, polysaccharides, polyesters, polyacrylamides, polyethers, polyurethane dispersions,

acrylic latex dispersions, and mixtures and copolymers thereof.

3. The device of claim 1, wherein said drug agent is selected from the group consisting of pharmaceutically active compounds, proteins, oligonucleotides, DNA compacting agents, recombinant nucleic acids, gene/vector systems, and nucleic acids.

4. The device of claim 1, wherein said sheath comprises a material selected from the group consisting of ethylene vinyl acetate, latexes, urethanes, polysiloxanes, styrene-ethylene/butylene-styrene block copolymers, aliphatic polyesters, and mixtures and copolymers thereof; and nitinol and stainless steel.

5. The device of claim 1, wherein said at least one perforation is in the shape of a longitudinal slit.

6. The device of claim 5, wherein said sheath comprises a plurality of perforations arranged in a staggered pattern.

7. The device of claim 1, wherein said substrate comprises at least part of a balloon portion of a balloon catheter.

8. The device of claim 7, wherein said sheath is tubular and surrounds said balloon portion of said balloon catheter, said tubular sheath having proximal and distal ends.

9. The device of claim 8, wherein said proximal and distal ends of said sheath are attached to said balloon catheter such that said balloon portion is completely covered by said sheath.

10. The device of claim 9, wherein said proximal and distal ends of said sheath are attached to said balloon catheter by an adhesive.

11. The device of claim 9, further comprising a filament around said proximal and distal ends of said sheath.

12. A method for the localized delivery of a drug agent to a target location within a mammalian body, comprising the steps of:

providing a medical device comprising:

a substrate that is expandable from a compressed state to an expanded state;

a coating on said substrate; and

a sheath over said coating, said sheath being expandable from a compressed state to an expanded state and having at least one perforation therein;

wherein when said substrate is in a compressed state, said sheath is in a compressed state and said at least one perforation is substantially closed; and

wherein when said substrate is in an expanded state, said sheath is in an expanded state and said at least one perforation in said expandable sheath is substantially open;

incorporating said drug agent into said coating;

delivering said medical device to said target location while said sheath is in a compressed state and said at least one perforation is substantially closed; and

expanding said substrate to thereby expand said sheath to an expanded state such that said at least one perforation is substantially open, whereby the drug agent passes through said at least one perforation.

13. The method of claim 12, wherein said step of incorporating the drug agent into said coating comprises the steps of:

expanding said substrate to thereby expand said sheath such that said at least one perforation is substantially open;

exposing said drug agent to said coating through said at least one perforation while said at least one perforation is substantially open; and

compressing said substrate to thereby compress said sheath such that said at least one perforation is substantially closed.

14. The method of claim 13, wherein said drug agent is exposed to said coating by immersing at least part of said medical device into a solution comprising said drug agent.

15. The method of claim 12, wherein said coating comprises a polymer selected from the group consisting of polycarboxylic acids, cellulosic polymers, gelatin, polyvinylpyrrolidone, maleic anhydride polymers, polyamides, polyvinyl alcohols, polyethylene oxides, glycosaminoglycans, polysaccharides, polyesters, polyacrylamides, polyethers, polyurethane dispersions, acrylic latex dispersions, and mixtures and copolymers thereof.

16. The method of claim 12, wherein said drug agent is selected from the group consisting of pharmaceutically active compounds, proteins, oligonucleotides, genes, DNA compacting agents, gene/vector systems, and nucleic acids.

17. The method of claim 12, wherein said sheath comprises a material selected from the group consisting of ethylene vinyl acetate, latexes, urethanes, polysiloxanes,

styrene-ethylene/butylene-styrene block copolymers, aliphatic polyesters, and mixtures and copolymers thereof; and nitinol and stainless steel.

18. The method of claim 12, wherein said at least one perforation is in the shape of a longitudinal slit.

19. The method of claim 18, wherein said at least one perforation comprises a plurality of perforations arranged in a staggered pattern.

20. The method of claim 12, wherein said substrate comprises at least part of a balloon portion of a balloon catheter.

21. The method of claim 20, wherein said sheath is tubular and surrounds said balloon portion of said balloon catheter, said tubular sheath having proximal and distal ends.

22. The method of claim 21, wherein said proximal and distal ends of said sheath are attached to said balloon catheter such that said balloon portion is completely covered by said sheath.

23. The method of claim 12, wherein said medical device comprises an electroporation catheter.

24. The method of claim 12, wherein said medical device comprises an iontophoresis catheter.

25. A medical device, comprising:

a catheter comprising a balloon portion that is expandable from a compressed state to an expanded state;

a polymer coating on said balloon portion, said coating having a drug agent incorporated therein; and

a tubular sheath over said coating, said sheath being expandable from a compressed state to an expanded state and having a plurality of perforations therein, said perforations being arranged in a staggered pattern; wherein

the proximal and distal ends of said sheath are attached to said catheter such that said balloon portion is completely covered by said sheath;

when said balloon portion is in a compressed state, said sheath is in a compressed state and said perforations are substantially closed such that said drug agent does not pass through said perforations; and

when said balloon portion is in an expanded state, said sheath is in an expanded state and said perforations are substantially open such that said drug agent passes through said perforations.